

REMARKS

Claims 13, 14, 16-18, 20, 22, 24, and 25-27 remain pending and under consideration in this application upon entry of the amendments contained herein. Claims 13 is currently amended. Support for the amendments to the claims lies in the specification as filed, for example, support for a dosage regime of cyclosporin A and 2-chlorodeoxyadenosine being administered can be found at least at page 10, line 27 to page 11, line 20; page 19, line 6 to page 22, line 2; Figures 3, 5, and 7; and Tables 2-8. No new matter has been added by virtue of the amendments contained herein.

Claim Rejection Under 35 U.S.C. §103 (a)

Applicant appreciates the Examiner's withdrawal of the rejection under 35 USC § 103(a) over the prior art of record in view of the amendment and remarks filed 6/12/07.

Applicant notes the Office Action asserted amendment to the claims resulting in overcoming the present rejections of record under 35 USC §112 would result in reinstatement of the rejection under 35 USC § 103(a). Applicant submits the presently amended claims have not been amended to render the subject matter now obvious in view of Nawrocki et al. (*Transplantation Proceedings*, 28: 3538-3539, 1996), Cramer et al. (*Transplantation Proceedings*, 29: 616, 1997) and Schmid et al. (*Eur. Surg. Res.*, 30: 61-68, 1998) and/or Kouwenhoven et al (*Transplant Int.* 13:385-401, 2000). Applicant submits the present claims remain patentable and non-obvious for the same reasons set forth in Applicant's prior response.

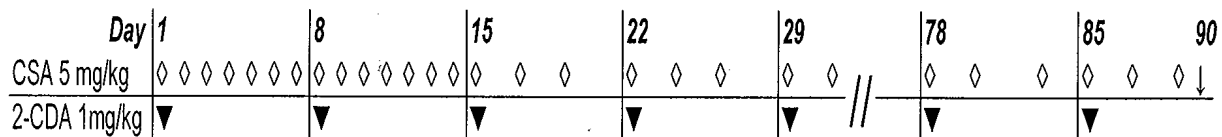
Claim Rejections Under 35 U.S.C. §112

35 USC §112, First paragraph

Claims 13, 14, 16-18, 20, 22, and 24 were rejected under 35 USC §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office Action maintains Claim 13 contains new matter because the specification does not appear to support the recitation "the administration of cyclosporin A (CSA) and 2-chlorodeoxyadenosine (2-CDA) to the allograft recipient in a coordinated dosage regime comprising days on which both CSA and 2-CDA are

administered and days on which only CSA is administered.” The Office Action asserts no alternative period was disclosed when both were given, followed by only one. See Office Action, page 4, first paragraph. Applicant respectfully disagrees with the conclusion asserted in the Office Action and traverses the rejection under 35 USC § 112, first paragraph.

Applicant appreciates the acknowledgment in the Office Action of disclosure of treatment regimens with various combinations. Applicant respectfully points out treatment regimens are provided which meet the limitation: “the administration of cyclosporin A (CSA) and 2-chlorodeoxyadenosine (2-CDA) to the allograft recipient in a coordinated dosage regime comprising days on which both CSA and 2-CDA are administered and days on which only CSA is administered.” In fact, the disclosure discussed in the Office Action at page 3, third paragraph through page 4, first paragraph is supportive of the recited limitation. For example, administration of 5 mg/kg body mass per day of CSA for two weeks and 5 mg/kg body mass of CSA for three times a week thereafter and a single dose of 1 mg/kg per week of 2-CDA does meet this limitation. For assistance, a three week period according to this regimen is depicted below:



At the first day of each week, both CSA and 2-CDA are administered (i.e., “days on which both CSA and 2-CDA are administered”); and other days in the week only CSA is administered (i.e., “days on which only CSA is administered”). Additional disclosure of treatment regimens in Example 2 provide alternative treatment regimens which are also supportive of the recitation. Applicant thus submits the recitation “the administration of cyclosporin A (CSA) and 2-chlorodeoxyadenosine (2-CDA) to the allograft recipient in a coordinated dosage regime comprising days on which both CSA and 2-CDA are administered and days on which only CSA is administered” is fully supported in the specification as filed and is not new matter. Reconsideration and withdrawal of the rejection is respectfully requested.

35 U.S.C. §112, Second paragraph

Claims 13, 14, 16-18, 20, 22, and 24 were rejected under 35 USC §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In an effort to advance prosecution, Claim 13 has been amended. It is believed the amendments address the concerns set forth in the Office Action under 35 USC §112, first paragraph. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

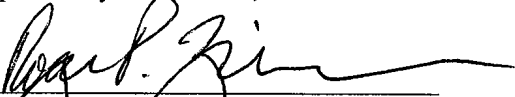
In light of the amendments and arguments presented herein, Applicant respectfully requests reconsideration and withdrawal of the outstanding rejection and allowance of the present claims under consideration. Early Notice to this effect is earnestly solicited in this case.

In the event a telephone discussion would be helpful in advancing the prosecution of the present case, Applicant requests the Examiner telephone the undersigned at (508) 860-1472.

This paper is being filed timely as it is being filed on or before the expiration of the shortened statutory period. It is believed no additional fees and/or extensions of time are required. In the event any additional extensions of time, fees and/or credits are necessary, please consider this a petition therefor. The undersigned hereby authorizes the requisite fees to be charged and/or credited accordingly to Deposit Account No. 50-1582.

November 12, 2007

Respectfully submitted,

By 

Roger P. Zimmerman
Registration No. 38,670
Direct tel.: (508) 860-1472

Mirick, O'Connell, DeMallie & Lougee, LLP
1700 West Park Drive
Westborough, Massachusetts 01581

Telephone: (508) 898-1501
Facsimile: (508) 898-1502